REMARKS/ARGUMENTS

In response to the pending Office Action of February 10, 2006, Applicant presents the following arguments and amendments. The present amendments are requested solely for the purpose of more clearly describing and claiming the present invention and do not introduce any new matter. Applicant submits that in light of the arguments and amendments presented, this application is in condition for allowance. Accordingly, entry of these amendments, reconsideration of all pending rejections and objections, and passage to allowance is respectfully requested. With the entry of this amendment, claims 35-61, and 69 - 77 are pending herein.

Amendments to the Claims

New claims 69 - 77 have been added to more clearly specify the claimed invention. The addition of new claims 69-77 does not introduce any new matter.

Support for new claim 69 is provided throughout the specification and in the claims as filed. Specific support for new claim 69 is provided by the description on page 28, lines 12 – 21 of the specification of an embodiment of the present invention wherein "the first-level alarm does not pause the platelet pump which controls fluid flow through the leukocyte reduction chamber" and "the second-level alarm . . . allows a slow-down period so that the leukocyte reduction system (LRS) can keep operating." New claim 69 does not introduce any new matter

Support for new claim 70 is provided by the description on page 30, lines 7 – 11 of the specification of an embodiment of the present invention wherein "[i]f plasma and platelet collection are finished . . . a third level alarm is triggered." New claim 70 does not introduce any new matter.

Support for new claims 71 and 73 is provided by the description on page 29, line 7 of the specification of an embodiment of the present invention wherein "[t]he third-

level alarm causes all pumps to stop." New claims 71 and 73 do not introduce any new matter.

Support for new claim 72 is provided by the description on page 31, lines 1 – 5 of the specification of an embodiment of the present invention wherein a third-level alarm condition is triggered "if, during the slow-down period of the second-level alarm condition, the pressure drops below P_S." New claim 72 does not introduce any new matter.

Support for new claim 74 is provided by the description on page 28, lines 22 – 27 of the specification of an embodiment of the present invention wherein "[t]he first-level alarm pauses all pumps (except the platelet pump which maintains flow through the leukocyte reduction system (LRS) chamber)." New claim 74 does not introduce any new matter.

Support for new claim 75 is provided by the description on page 28, lines 28 – 30 of the specification of an embodiment of the present invention wherein "[t]he second-level alarm causes the inlet pump flow and anticoagulant pump flow to be reduced, e.g., by a specified flow-reduction factor, while maintaining flow through the LRS chamber." New claim 75 does not introduce any new matter.

Support for new claim 76 is provided by the description on page 29, lines 3 – 6 of the specification of an embodiment of the present invention wherein the specified flow-reduction factor is "low enough to keep from triggering another first-level alarm, but high enough so that flow through the LRS chamber is maintained." New claim 76 does not introduce any new matter.

Support for new claim 77 is provided by the description on page 29, line 3 of the specification of an embodiment of the present invention wherein the "specified flow-reduction factor is preferably about 0.5 (flow rate is reduced by half)." New claim 77 does not introduce any new matter.

Rejections under 35 U.S.C. § 112, Second paragraph

Claims 39, 40 and 43 are rejected under 35 U.S.C. 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." In support of the rejection of claims 39 and 40, the Examiner characterizes the rejected claims as incomplete for omitting "components of the claimed device that measure hematocrit levels and flow rates" for the calculations required by the limitations of the claims.

Applicants respectfully disagree with the rejections of claims 39 and 40 under 35 U.S.C. 112, second paragraph. Therefore, reconsideration and withdrawal of these rejections in light of the present arguments is respectfully requested. In addition, Applicants seek clarification as to the nature of the rejection of pending claim 43, as this claim does not include an algorithm involving system parameters, such as flow rates and/or hematocrit levels.

Applicants note that the system parameters set forth in claims 39 and 40 are not necessarily measured parameters. Rather, in useful embodiments of the present invention they are pre-selected, set and controlled rather than measured. Consequently, control of the pumps and of the rotor speed are all the structure that is necessary. Another sensor, distinct from the pressure sensor, is not necessary. For example, a hematocrit of 75% may be achieved not by measurement, but by setting flow rates and controlling the rotor speed (*See,* page 45, line 3, and 18-25 of the specification). The desired AC ratio is achieved by controlling the inlet flow rate and the AC flow rate, that is, by controlling the pump speeds. (*See*, Page 45, lines 5-7). Therefore, flow rate in the needle, for example, is not measured directly, but is calculated based on the speed of the pumps contributing to flow in the needle and the size of the needle. Claims 39 and 40 specify important "system parameters", not system measurements. Consequently, no further "structure", such as a flow meter, is required.

Rejections under 35 U.S.C. § 103

Claims 35-61 are rejected under Section 103(a) as allegedly unpatentable over U.S. Patent No. 5,954,971 (Pages *et al.*) in view of U.S. Patent No. 5,423,746 (Burkett *et al*). In support of this rejection, the Examiner characterizes Pages *et al.* as teaching "the apparatus substantially as claimed by the Applicant" but failing "to disclose that the processor is programmed to count the first-level alarms and trigger a second level alarm within a specified period of accumulated first level alarms." Examiner further characterizes Burkett *et al.* as disclosing "a system that uses a microprocessor and alarm system to indicate when the measured pressure from pressure transducer **62** exceeds a programmed value" wherein "[a] green light indicates a functioning infusion site, a yellow light may be used to indicate an initial or transitory condition; and a red light an/or audible signal may be used to indicate that a number of consecutive tests have resulted in alarm conditions." With respect to the combined teaching of these references, the Examiner concludes that:

> [i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to program the controller and microprocessor disclosed by Pages with the primary and secondary alarm sequence program disclosed by Burkett, in order to alert the operator to an urgent condition requiring immediate attention, as taught by Burkett."

Applicants request reconsideration and withdrawal of the present rejections in light of the following arguments.

The inventions of rejected claims 35-61 provide a fluid separation device having a two-level alarm system capable of providing sophisticated detection and flow control functionality useful for blood processing applications. This highly specialized functionality principally arises from a combination of: (i) specific flow control responses for first-level and second-level alarm conditions provided to maintain and/or restore system operation during pressure fluctuations, and (ii) distinct first-level and second-level alarm conditions that are initiated upon specific changes in system pressure useful for distinguishing serious problems requiring operator intervention from transient pressure fluctuations. Benefits provided by the present two-level alarm system include

minimizing operator intervention and system oversight while maintaining flow conditions necessary for effective processing (*See,* pg. 5, lines 1 – 5 & pg. 22, lines 17 – 22 of specification). This aspect of the present invention is significant as maintaining flow conditions during processing is frequently essential for preserving and/or optimizing the quality and purity of collected fluid components, particularly in the context of blood processing and separation.

In support of the present rejections, Examiner characterizes Pages *et al.* as disclosing a system capable of generating an alarm signal in response to pressure fluctuations, and Burkett *et al.* as disclosing a "primary and secondary alarm sequence" which when combined with the teaching in Pages *et al.* renders claims 38-61 obvious. Applicants respectfully disagree with this characterization, as neither Pages *et al.* nor Burkett et al disclose, or even suggest, the present alarm system having the claimed: (i) flow control response functionality and (ii) two level alarm conditions initiated upon specific changes in system pressure.

First, Pages *et al.* and Burkett *et al.* do not disclose a two-level alarm system having flow control response functionality wherein a first-level alarm-triggering signal causes the "flow controller to **pause fluid flow** . . . for a specified delay time" and wherein a second-level alarm-triggering signal causes the "flow controller to **slow down fluid flow rate**" in the system. The single alarm system provided in Pages *et al.* is limited to a complete shut down flow control response wherein "pump **132** is stopped and/or an alarm activated." (*See*, col. 5, lines 7 - 11 of Pages *et al.*). The alarm system of Burkett *et al.*, on the other hand, is provided with a first-level response limited to "appropriate visible and audible displays" and providing "an automatic increase in the test sequence frequency." (*See*, col. 11, lines 11-13 & 22 – 25 of Burkett *et al.*). Nowhere in either of these references is a first-level alarm response of pausing fluid flow for a specified time mentioned or even suggested. Moreover, Pages *et al.* does not provide for a second-level alarm state and, thus, no corresponding second-level alarm flow response is disclosed or even contemplated. Burkett *et al.*, on the other hand, is limited to a second-level alarm response that does not involve varying system flow

conditions, such as slowing the system flow rate as expressly provided in the rejected claims. Rather, Burkett is limited to a second-level alarm response providing a "display of a red light **44** and sounding of a second type of audible alarm." Accordingly, Pages *et al.* and Burkett *et al.* do not teach or even suggest use of the specific first-level alarm condition and second-level alarm condition flow control responses expressly provided in the rejected claims, let alone the combination of these important claim limitations. Claims 35-61 are not rendered obvious by the cited references because Pages *et al.* and Burkett *et al.* fail to teach, enable or suggest all the limitations in the amended claims, particularly a first-level alarm flow control response of pausing fluid flow and a second-level alarm flow control response of slowing the system flow rate, and the missing claim limitations are well outside the grasped of the typical artisan at the time of invention. *See, e.g.*, In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). It is therefore submitted that no *prima facie* case of obviousness has been made out with respect to this rejection, and reconsideration withdrawal thereof is respectfully requested.

Second, Pages *et al.* and Burkett *et al.* do not disclose an alarm system "programmed to count the number of first-level alarm triggering signals generated **within a specified period** and generate a second-level alarm triggering signal when a specified number of such first-level alarm triggering signals have been generated within said **specified period**." (*See*, claim 35 emphasis added). The alarm system disclosed in Pages *et al.* is limited to a feedback circuit that provides a single alarm state triggered by pressure fluctuations exceeding predeteremined values, and therefore, does not disclose conditions for initiating a second-level alarm condition. (*See*, "Controller **155** can also be provided with an alarm function that alerts the system operator . . . and/or shuts down the pump **132** if the measured pressure exceeds a maximum limit." & "if, however, P_a exceeds, P_{max} at any point, the system enters the alarm state **315**" Col. 4, lines 36 – 39 & Col. 5, lines 8 – 10 of Pages *et al.*). Although Burkett *et al.* arguably does disclose an alarm system having first and second levels, the second-level alarm state is initiated "[i]f a selected number . . . of these more frequent automatic sequences results in infiltration indications." (*See*, col. 11, lines 24 – 30 of Burkett *et al.*).

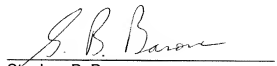
Moreover, the second-level alarm in Burkett *et al.* is based on measured variations in system pressure recovery times, in contrast to initiating a second-level alarm level on the basis of measured decreases in system pressure over a specified time period as provided in the rejected claims. Accordingly, Pages *et al.* and Burkett *et al.* do not teach or even suggest use of a specified time frame over which decreases in system pressure are counted so as to initiate a second-level alarm condition. Claims 35-61 are not rendered obvious by the cited references because Pages *et al.* and Burket *et al.* fail to teach, enable or suggest all the limitations in the amended claims, particularly that a specified number of first-level alarm signals first-level alarm condition must be generated within a specified period of time to initiate a second-level alarm condition, and the missing claim limitations are well outside the grasped of the typical artisan at the time of invention. *See, e.g.*, In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). It is therefore submitted that no *prima facie* case of obviousness has been made out with respect to this rejection, and reconsideration withdrawal thereof is respectfully requested.

CONCLUSION

In view of the foregoing arguments, this case is considered to be in condition for allowance and passage to issuance is respectfully requested. If new issues of patentability are raised, the Examiner is invited to call and arrange for an opportunity to discuss these issues via phone interview.

It is believed that no fee is required with this submission. If this is incorrect, however, please deduct the appropriate fees for this submission along with any extension of time required from Deposit Account No. 07-1969.

Respectfully submitted,



Stephen B. Barone
Reg. No. 53,968
Customer No. 23713

GREENLEE, WINNER AND SULLIVAN, P.C.
4875 Pearl East Circle, Suite 200
Boulder, CO 80301
Telephone: (303) 499-8080
Facsimile: (303) 499-8089
E-mail: winner@greenwin.com
Attorney Docket No. 109-03